

### ***Remarks***

Reconsideration and allowance of this Application is respectfully requested. Upon entry of the foregoing amendment, claims 1-2, 4-11 and 14-46 are pending in the application. Claims 15-36 and 38-40 were withdrawn from consideration due to a restriction requirement. Claims 1-2, 4-11, 37 and 41-46 are under consideration, with claims 1 and 43 being the independent claims.

Support for the claim amendments can be found throughout the specification and the claims as originally filed. Specifically, support for the amendment to claim 1 can be found on page 32 of the specification. Support for new claim 43 can be found on pages 7 and 32 of the specification. Support for new claims 41-46 can be found on pages 31-32 of the specification.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

### ***Objection to the Disclosure***

In the Office Action, at page 3, the Examiner objected to the disclosure for apparently containing a typographic error in line 9 of page 7, wherein the word "functional" should have been "binding." By the foregoing amendment, Applicants have corrected the specification in accordingly.

In the Office Action, at page 3, the Examiner objected to the abstract of the disclosure because of the presence of materials on the page of the abstract that are not related to the disclosure. Applicants herewith submit a corrected substitute abstract page.

### ***Drawings***

In the Office Action, at page 3, the Examiner noted that corrected drawing have not yet been received by the PTO. Applicants herewith submit a corrected set of drawings in accordance with the comments on from PTO-948 that was attached to Paper No. 18, of November 6, 2002.

***Rejections under 35 U.S.C. § 112, first paragraph***

In the Office Action, at page 3, claims 1-11, 14, 37 and 41-42 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. The Examiner stated that "there is no specific functional limitation for the claimed compounds." By the foregoing amendment, Applicants canceled claim 3, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claims to make explicit that which was implicit.

By the foregoing amendments, Applicants have clarified that the invention is directed to polypeptides that can stimulate intracellular cAMP accumulation. Thus, the amended claims clarify the biological function of the polypeptides of the present invention.

In the Office Action, at page 4, claims 7-9 were rejected over the recitation of the phrase "functional derivatives" therein. Solely in an effort to expedite prosecution, Applicants have amended claims 7 and 8 to delete the recitation of "functional derivatives" and instead added new dependent claims 44 and 45 in which modifications to the polypeptides of claims 7 and 8 are defined both functionally and structurally. Function is provided by the language "wherein said polypeptide is modified to improve the solubility, absorption, or biological half-life of said polypeptide," while structure is provided by the language "wherein said modification is selected from the group consisting of the addition of C<sub>1-12</sub> alkyl groups, the addition of C<sub>1-12</sub> hydroxyalkyl groups, the addition of acyl groups, and lactam cyclization." Applicants note that they are not required to provide experimental examples of each and every polypeptide that would fall under the scope of the claims. *See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1237, quoting *In re Angstadt*, 537 F.2d 498, 502, 190 U.S.P.Q. (BNA) 214, 218 (CCPA 1976) ("it is not necessary that a patent applicant test all the embodiments of his invention. . . . what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims.").

In the Office Action, at page 4, the claims were rejected for allegedly reciting an undefined linker. Applicants respectfully disagree with the Examiner's characterization. However, solely in an effort to expedite prosecution, and without acquiescing with the

propriety of the rejection, Applicants have amended the claims to recite linkers that are composed of either greater than 1 repeats of the same amino acid molecule, or 1 to 9 repeats of an aliphatic diamine molecule.

In the Office Action, at page 4, claims 7-9 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Specifically, the Examiner stated that claims 7-9 recite "functional derivatives" and that the claims do not require that the "functional derivatives" possess any particular conserved structure or disclosed distinguishing feature. Applicants respectfully traverse this rejection. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended claims 7 and 8 to delete the recitation of "functional derivatives" and instead added new dependent claims 44 and 45 in which modifications to the polypeptides of claims 7 and 8 are defined both functionally and structurally.

Applicants respectfully draw the Examiner's attention to at least pages 21, lines 7-28, and page 31, line 18, to page 32, line 2, of the specification. In those pages, Applicants have provided an ample description of the functional limitations of the modifications that are commensurate with the scope of the invention. Moreover, pages 31-32 of the specification contain a detailed list exemplifying the possible chemical derivatives of the invention. Applicants respectfully submit that these disclosures amply satisfy the written description requirement and demonstrate that Applicants were in possession of the invention as of the time.

In view of the foregoing amendments, Applicants respectfully request that the rejections of claims 1-2, 4-11, 14, 37 and 41-42 under 35 U.S.C. § 112, first paragraph, be withdrawn.

***Rejections under 35 U.S.C. § 112, second paragraph***

In the Office Action, at page 4, claims 1-11, 14, 37 and 41-42 were rejected under 35 U.S.C. § 112, second paragraph, for being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically the Examiner objected to the term "substantially similar."

By the foregoing amendment, Applicants canceled claim 3, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims.

Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended the claims to remove the term "substantially similar" and to specify that the compounds of the present invention stimulate intracellular cAMP accumulation.

In view of the foregoing amendments, Applicants respectfully request that the rejection of claims 1-2, 4-11, 14, 37 and 41-42 under 35 U.S.C. § 112, second paragraph, be withdrawn.

***Rejections under 35 U.S.C. § 102 (b),***

In the Office Action, at page 7, claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Caulfield *et al.* (Endocrinology, 127:83-87, 1990). The Examiner stated that Caulfield *et al.* teach a parathyroid hormone fragment, PTH(1-34), and that if n in the formula S-(L)n-B is equal to 1, as permitted by the claims, the formula will become S-L-B, and could read on PTH(1-34). By the forgoing amendment, Applicants canceled claim 3, thus rendering its rejection moot. Applicants respectfully traverse the rejection as it may apply to the remaining claims. Solely in an effort to expedite prosecution, and without acquiescing with the propriety of the rejection, Applicants have amended claim 1 to recite linkers that are composed of more than 1 repeat of the same amino acid molecule, and added new claim 43 to recite 1 to 9 repeats of an aliphatic diamine molecule. Thus, Caulfield *et al.* fails to anticipate claims 1 or 2.

In view of the foregoing amendments, Applicants respectfully request that the rejection of claims 1-2, under 35 U.S.C. § 102(b), be withdrawn.

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lawrence B. Bugaisky  
Attorney for Applicants  
Registration No. 35,086

Date: Sept 7, 2004

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600